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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,160	10/12/2005	Werner Gehringer	37998-237519	7155

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1656	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,160	GEHRINGER ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 16, 2009 has been entered.

Claims 1-11 have been cancelled. Claims 13-15 have been added. Claims 12-15 are currently pending and are under examination.

Benefit of priority is to November 25, 2002.

Maintenance of Rejections:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 12 and new Claims 13-15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., "*Purification of human albumin by the combination of the method of Cohn with liquid chromatography,*" Brazilian Journal and Biological Research, 1998, 31, pages 1383-1388 in view of Tanaka et al., "*High quality human immunoglobulin G purified from Cohn fractions by liquid chromatography*,"

Brazilian Journal and Biological Research, 2000, 33, pages 27-30 and Matejtschuk et al., *"Production of human albumin solution: a continually developing colloid,"* British Journal of Anaesthesia 2000, 85, vol. 6, pages 887-95.

In the Abstract of the "*Purification of human albumin by the combination of the method of Cohn with liquid chromatography,*" Tanaka et al. teach large volumes of plasma that can be fractionated by the method of Cohn where the first precipitate containing fractions I and II and III (step (a) of claim 12, Cohn fractionation to form first fraction).

In the Abstract, Tanaka et al. teach that the supernatant of fraction I and II and II was submitted to a second precipitation and fraction IV was obtained, where albumin was obtained from the supernatant of the precipitate of fraction IV (step (b) of claim 12, concentrated fraction).

In the Abstract, Tanaka et al. teach that the viral inactivation was performed by pasteurization at 60°C for 10 hours (step (c) of claim 12, pasteurization, and step (d) filing vials with the pasteurized fraction and claim 12).

In the Abstract, Tanaka et al. teach that the Prekallikrein activator (PKA) levels were less or equal 5 IU/ml. (step (e) where the PKA content was of less than 12 IU/ml).

Tanaka et al. does not teach incubation of the vials for 10 days at 30°C to 32°C or four weeks at 20°C to 25°C (step (d) of claim 12).

In the Abstract of "*High quality human immunoglobulin G purified from Cohn fractions by liquid chromatography*," Tanaka et al. teach that in order to obtain a high quality of peptides, i.e. immunoglobulin from pastes prepared from Cohn method, viral

inactivation was performed by incubating the preparation with pepsin at 35°C for 18 hours, for example, where the PKA value was less than 5 IU/ml (step (e) from claim 12).

Matejtschuk et al. teach in Figure 1, page 888, different methods for the preparation of plasma protein fraction and human albumin solution, where different fractions, including paste V, Cohn fractionation is diagramed (step (a) of claim 12 as referring specifically to fraction V).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method of manufacturing of an albumin where the PKA is less than 12 IU/ml (as taught by Tanaka et al.) when produced by the Cohn fractionation (Tanaka et al. and Matejtschuk et al.) and where the incubation takes place at 35°C (Tanaka et al.) because Cohn fractionation process, including fraction V, is known in the art for the purpose of preparation of protein fractions, and the PKA value is 12 IU/ml. Further, one would be motivated to add additional steps in the method to optimize desired conditions i.e. temperature of incubation being in the range of 20°C to 32°C, or the time of incubation, for example. Therefore, the invention is *prima facie* obvious.

Applicants urge that Claim 12 refers to those steps recited in Claim 12 plus any non-material additions. The Declaration of Katarina Pock has been submitted and indicates that chromatographic steps such as those taught in the prior art, would be considered to be a material addition to the method of Claim 12.

The Declaration of Katarina Pock has been carefully reviewed. Dr. Pock states (para. 4) that the addition of a chromatographic purification step into the claimed method would be considered a material addition to the method (and therefore not be a step in view of the transitional phrase "consisting essentially of"). At para. 5, Dr. Pock discusses the economical and workload advantages to excluding the chromatographic steps. In paras 6-8, Dr. Pock compares and contrasts the methods used in each reference in turn; however, it is not what each reference teaches but what together the references teach one of ordinary skill in the art. While the Examiner appreciates Dr. Pock's views and discussion, what is lacking is how excluding the chromatographic steps changes the outcome of the method claimed (see also the interview summary April 8, 2009, last sentence). If the outcome is not affected by the exclusion of the chromatographic steps, then it is concluded that the chromatographic steps are not essential to the manufacturing of an albumin enriched fraction having reduced PKA content as set forth in Claim 12.

Applicants may wish to change their language from "consisting essentially of" to ---- consisting of ----, or adding language that excludes chromatographic steps. For example:

---A method of manufacturing an albumin enriched fraction having reduced PKA content, said method conducted without chromatographic steps, said method consisting essentially of...---

If Applicants amend their claims to include this exclusion language, Applicants should be careful that such exclusion does not add new matter.

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 6:00 AM - 4:00 PM, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656